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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiff,

VS.

PAUL S. AISEN, et al.,

Defendants.

CASE NO. 15-cv-1766-BEN (BLM)

ORDER DENYING PLAINTIFF'S MOTION FOR CONTEMPT SANCTIONS

I. INTRODUCTION

Now before the Court is the Plaintiff's Motion for Contempt Sanctions, or in the Alternative for Issuance of an Order to Show Cause Re Contempt Against Defendants Aisen, Jimenez-Maggiora, and University of Southern California. Plaintiff alleges that these Defendants have not complied with the directions in the preliminary injunction issued on August 4, 2015. Plaintiff asserts that, "more than three months after the issuance of the [preliminary injunction order], Defendants have utterly failed and refused to comply with its plain terms." Mot. for Contempt, at 2. Defendants deny the claim. Plaintiff has not carried its burden. Therefore, the motion for contempt sanctions is denied.

II. APPLICABLE LAW

The force and vitality of a judicial decree derives from robust sanctions.

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¹The parties are familiar with the events leading up to this litigation and the contents of the preliminary injunction order issued by the Superior Court of California. There is no dispute that the preliminary injunction entered by the state court continued in full force when the case was removed to this Court, pursuant to 28 U.S.C. § 1450.

McComb v. Jacksonville Paper Co., 336 U.S. 187, 191 (1947). Courts have inherent power to enforce compliance with a lawful order through the mechanism of civil contempt. Spallone v. United States, 493 U.S. 265, 276 (1990). In the Ninth Circuit, the test of whether a party is in contempt of a court order is clear: "[t]his Circuit's rule with regard to contempt has long been whether the defendants have performed 'all reasonable steps within their power to insure compliance' with the court's orders." Stone v. City and Cnty. of S.F., 968 F.2d 850, 856 (9th Cir. 1992) (emphasis added). The steps to be performed must be within a defendant's power, and the steps must be a reasonable step to take.

Plaintiff asserts that defendants Paul S. Aisen, M.D., Gustavo Jimenez-Maggiora, and the University of Southern California have failed to take all reasonable steps to comply with the preliminary injunction order. Plaintiff is the moving party. Therefore, the plaintiff has the initial burden.

The plaintiff's burden is to show by clear and convincing evidence a violation of the order.² The violation must be of a specific and definite order of the court. Id. at n.9 ("The moving party has the burden of showing by clear and convincing evidence that the contemnors violated a specific and definite order of the court.") (citation omitted). If the moving party (in this case, the plaintiff) satisfies its burden of showing, then the burden shifts to the purported contemnors. The purported contemnors then have the burden "to demonstrate why they were unable to comply." *Id.* Put differently, the purported contemnors may show "they took every reasonable step to comply." *Id.*

III. THE PRELIMINARY INJUNCTION ORDER

The difficulty with this type of case stems from the medical delicacy and

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²Exhibits placed in the record are plentiful. Plaintiff's motion includes 384 pages of exhibits and often refers to exhibits found among 3,112 pages attached to the Notice of Removal and 324 pages of its Opposition to Defendants' motion to modify. For its own part, the opposing parties include 386 pages of their own exhibits. Most of these exhibits, however, have little direct significance on the question of contempt.

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technological complexity of the Alzheimer's Disease Cooperative Study ("ADCS") Data and Systems which is the subject of the preliminary injunction order. Contempt requires disobedience to an order that is *specific and definite*, but the preliminary injunction order contains few specific and definite directions. The preliminary injunction order was crafted in such a way as to safeguard from destruction a significant public resource: longitudinal medical research and its informational databases about treatments for Alzheimer's Disease. Because the informational databases include computer data files, they must be managed by experts in digital technology. Because the studies are ongoing, disruptions in data access or loss of data may have serious adverse impacts on Alzheimer's patients.

While the preliminary injunction order contemplates restoration to the status quo ante, it also recognizes that restoration must be accomplished through a careful and deliberate process. PI Order at ¶2 ("The gathering, sorting, storage, analysis and management of data are all essential aspects of the Alzheimer's Disease Cooperative Study (ADCS). In order to maintain the status quo, these functions must be performed to avoid the likelihood of damage to the study and to enable the study to continue to move forward to achieve its stated goals."). That takes deliberation. Deliberation takes time. The preliminary injunction order takes special care to avoid a hasty operation that may kill "the patient." It orders Defendants to restore management and control to Plaintiff "employ[ing] all deliberate speed. . . ." Id. at ¶1. To that end, a Special Master was appointed to oversee the process and a medical expert was appointed to lend assistance to the Special Master. The Special Master is authorized to seek the Court's assistance. And the Special Master has sought clarification of the preliminary injunction order. This motion for contempt was filed, however, before the Court responded to the Special Master's clarification request.

Further complicating the picture, the preliminary injunction order anticipates

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change. It anticipates that a study sponsor (the term "third party" is used in the text) may assign its rights to obtain access, custody, or control over the ADCS data, and it may assign its rights to the Defendants. *Id.* It appears that five of the six major study sponsors did make that change early on. The result is a complex web of legal relations which require the precision of a scalpel. Plaintiff does not make its case by simply claiming contempt. Here, the alleged contemnors may be acting legitimately on behalf of other rights-holders while maintaining custody and control over ADCS data.

Medical research is complicated. Large scale data management is complicated. Courts are not well-equipped with expertise in medicine or information technology. For example, this Court has never seen a "Github" or carried anything in a "Bitbucket." Yet, the Court has fashioned a preliminary injunction that attempts to transfer access for the ADCS Data and Systems, its Amazon Clouds, Githubs, and Bitbuckets, without destroying the on-going research. Questions are inevitable.

IV. CLARIFICATIONS OR MODIFICATIONS

Defendants have done what the Supreme Court teaches: when questions arise, seek clarification or modification from the issuing court. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192 (1949) ("Yet if there were extenuating circumstances or if the decree was too burdensome in operation, there was a method of relief. . . . Respondents could have petitioned the District Court for a modification, clarification or construction of the order."); *Regal Knitwear Co. v. NLRB*, 324 U.S. 9, 15 (1945) ("If defendants enter upon transactions which raise doubts as to the applicability of the injunction, they may petition the court granting it for a modification or construction of the order."). Defendants filed a motion for clarification or modification not long after questions were raised by the Special Master. The motion for contempt, however, was filed before the Court resolved the

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Defendants' motion. "[C]ourts no less than parties desire to avoid unwitting contempts, as well as to punish deliberate ones." *Regal*, 324 U.S. at 15.

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To sum up, in a civil contempt motion, "the moving party has the burden of showing by clear and convincing evidence that the contemnors violated a specific and definite order of the court." *Federal Trade Comm'n v. Enforma Natural Prods., Inc.*, 362 F.3d 1204, 1211 (9th Cir. 2004) (citations omitted). Plaintiff has not carried its burden. To see why the movant's burden has not been met, some examples will suffice.

V. PARTICULAR CLAIMS OF CONTEMPT

Plaintiff's first claim of contempt with a supporting document begins at page eight of the motion. Plaintiff asserts, "[a]t no point have Defendants complied with the [preliminary injunction order], or even proposed any plan or timetable for Defendants to 'return full system and data access, control and management of the ADCS Data and Systems to UCSD' as required by paragraph 1 of the Order." Mot. for Contempt, at 8. Plaintiff cites in support a declaration of Plaintiff's own lead attorney, J. Daniel Sharp, Esq. There is no other evidence offered. A strong case would present declarations from knowledgeable disinterested persons. Those persons would have knowledge of the time necessary and the medical-technological expertise necessary to actually accomplish the return of the ADCS Data and Systems as defined by the order. They would then opine about whether the process could have been completed sooner, if done with deliberate speed and without risking the integrity of the medical studies or the health of the patients in the studies. If the evidence was sufficient, the burden would then shift to the alleged contemnors. The declaration by movant's own counsel does not make a strong case here.

Plaintiff next asserts contempt because "Defendants have demanded continued access to the ADCS Data and Systems." *Id.* at 8-9. Plaintiff again cites

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the Sharp declaration. The problem is that the preliminary injunction order does not preclude Defendants from simply having access. The order presumes Defendants have access. The preliminary injunction orders that system and data access be returned to Plaintiff; it does not prohibit Defendants from having initial access or maintaining access. Moreover, it does not preclude a study sponsor from assigning its own access rights to Defendants. Thus, the claim that Defendants seek continuing access, even if proven, does not prove a contemptous violation of the order.

Plaintiff next asserts that Defendants are in contempt because Defendants "demanded this access for the express purpose of using the Data and Systems to 'continue running the studies.'" *Id.* at 9. Plaintiff cites the Sharp declaration. Again, the preliminary injunction order does not prohibit the defendants from running studies or accessing the study data. Instead, it requires the essential aspects of the study (the 'gathering, sorting, storage, analysis and managements of data") to continue to be performed to avoid damage to the ADCS study. Thus, the assertion, if true, does not evidence contempt.

Plaintiff next asserts that the Special Master requested a proposal to effectuate the transfer of control of the ADCS Data and Systems, but that the Defendants proposal of a "ring fence" was arguably in conflict with the preliminary injunction order. The Special Master did observe that the ring fence proposal "arguably conflicts" with the order. This is one subject of the Special Master's request for court assistance and Defendant's motion for clarification. Much more than the existence of a genuine question is required to show a clear and convincing contempt of court.

Plaintiff next asserts that defense *counsel* has "acted affirmatively to exclude UCSD" because counsel "advocated" with the Special Master to prevent Plaintiff from accessing a Github account containing information that is part of the ADCS.

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The preliminary injunction order includes mention of web-based data repositories such as Github and Bitbucket. But the preliminary injunction order placed the Special Master in charge of the delicate process of transferring management and control of the data and system used for the ADCS. The attorney advocacy to which Plaintiff refers appears to be an early request to the Special Master to ensure the Github control was part of the Special Master's planned transition process. The advocacy was apparently triggered by what appeared to possibly be Plaintiff's own self-help efforts to re-take Github control outside the process. Decl. of J. Daniel Sharp in Supp. of Opp'n. to Defs.' Mot. to Clarify or Modify the Prelim. Inj. (filed 9/29/15), Ex. A (Dkt. #31-4 at 6). It is easy to see that this is not clear and convincing evidence of Defendants' contempt.

Plaintiff asserts that Defendants "violated the [preliminary injunction order] by refusing UCSD's request of documentation and information about the ADCS Data and Systems." Plaintiff cites in support Sharp's email communication of 8/20/15 to defense counsel.³ Plaintiff then cites part of defense counsel's response

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³ Sharp's email states, "...listed below is a summary of items that UCSD would like to request as an initial priority from a technical perspective." The language of the email is difficult to understand by those not well-versed in the techno-jargon of information technology:

^{1.} Access to all the latest code repositories. This includes git/mercurial repositories stored in GitHub/Bitbucket and/or other locations. This also includes all branches in each repository as well as any forks that were made to other GitHub/Bitbucket accounts. Although USC provided a version of some of the code, it doesn't seem to be the latest version of the code and it doesn't include a commit history that would contain more information about how the code was architected over time. We should be given administrator access to the GitHub/Bitbucket accounts, similar to what we received for Amazon. In addition to all the repositories, it would be prudent to have from Defendants a description of each repository's contents, its purpose and whether it contains sensitive information that may damage the studies. If our access will damage the studies, we want to specifically know why. In general if the study integrity alarm is raised moving forward in response to any request, we need to know specifically why this is a concern.

^{2.} A detailed description of all the systems and their interactions, described using visual flow diagrams. We want this so we may understand once and for all where all the systems are and how they interact. This includes systems hosted at AWS, SDSC, ADCS, Google, GitHub/Bitbucket and anywhere else we may not know about. We would want information not only on the system contents and specs, but also the user

of 8/26/15 (i.e., "[w]e never agreed to provide all of the information requested in Mr. Sharp's email and we were never directed to do so"). Defense counsel's email response goes into more explanation for why and notes that most of the requested information was already within UCSD's ambit.⁴ This is not clear and convincing evidence of contempt.

Plaintiff asserts that Defendants refused to discuss the Special Master's proposal for a path forward. Plaintiff again cites attorney Sharp's own declaration and a string of emails between the Special Master and counsel for both parties. Without repeating all of the discussions relayed by the emails, it is clear from the email string that defense counsel was, in fact, discussing the proposed path forward in a manner in which one would expect counsel to discuss an important proposal.

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accounts, credentials, access levels and protocols used by each. This includes the direction of the interactions as well as full list of automated or manual processes that are required to maintain them. Which systems send out automatic notifications and for what purposes is also important. Claudiu put together quickly some examples of what we mean by visual flow diagrams (see attached).

3. Login credentials to and detailed descriptions of the TCAD test/dev environments.

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We want this because we want to begin understanding right away how this study is configured using the EDC so we may best maintain it when we receive it. We would also want a description of all the EDC modules (including versions and their location in the code repositories) in use by the TCAD portal as well and assurances that gaining access to the test/dev environments for TCAD will not damage study integrity. Again, if gaining access will endeager study integrity when a if gaining access will endanger study integrity, we want to know specifically why so that we may avoid this risk as expediently as possible. We will eventually want credentials and descriptions for all study EDCs, but TCAD is the priority due to obvious reasons (Toyama has repeatedly confirmed that it will not move the TCAD study from UCSD).

^{4.} A detailed description of the contents of the safe at ADCS, as well as the combination to open it should we need access. We want this so that we have complete access to everything physically stored at the ADCS should we need it.

5. A detailed history of all the Part11/HIPAA/etc. audits done of the EDC/CTMS/ADCS by third parties over the history of the ADCS. We want this because no one remaining at the ADCS as far as I can tell knows exactly what was done in this regard and it is critical on many levels to know these facts precisely."

⁴ "The proposal we submitted is exactly the proposal we agreed to submit at the end of our call on August 20th. We never agreed to provide all of the information requested in Mr. Sharp's email and we were never directed to do so. We have already provided a list of all of the documentation that UCSD has access to which covers most of the information requested. Our proposal is intended to implement the remaining aspects of the Court's order in an orderly manner, while preventing unreasonable risk of harm to the continuation of the studies, as the Court directed."

See Decl. of J. Daniel Sharp in Supp. of Opp'n. to Defs.' Mot. to Clarify or Modify the Prelim. Inj. (filed 9/29/15), Ex. D (Dkt. #31-4 at 28-38). This is not clear and convincing evidence of contempt.

Plaintiff asserts that Defendants "refused to comply in any way" with a September 5, 2015 directive of the Special Master. Plaintiff cites Exhibit E to attorney Sharp's declaration. Exhibit E is another email string; this time the emails are between counsel and the Special Master. Defense counsel writes only that he is discussing the implications of the directive with his client, not that his clients are refusing to comply. This is not clear and convincing evidence of contempt.

Plaintiff asserts that defendant Jimenez-Maggiora violated paragraph two of the preliminary injunction order by copying some files from "ades-adni2.iades.org." Plaintiff does not specify the specific and definite part of the order allegedly violated. Paragraph two of the preliminary injunction order does not mention "ades-adni2.iades.org," nor is it mentioned in any other place of which the Court is aware. The preliminary injunction order does prohibit Defendants from "exercising dominion, custody, and control over the ADCS Data and Systems." Assuming for the moment that data files found at "ades-adni2.iades.org" are part of the ADCS Data and Systems, Plaintiff assumes without citation that the action of copying files would be a contemptuous exercise of dominion, custody, and control.⁵ In support,

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⁵ The terms "dominion," "custody," and "control" are words that have long been associated with the common law tort of conversion or trover. Conversion, in turn, has historically applied to tangible things (*i.e.*, chattel). *Kremen v. Cohen*, 327 F.3d 1024, 1030 (9th Cir. 2003). One who exerts authority over another's physical property – a barrel of flour for instance – and delivers it to another, dispossesses the true owner and prevents the true owner from selling the barrel of flour. *E.g., Vasse v. Smith*, 10 U.S. (6 Cranch) 226, 232-233 (1810) (defendant converted 70 barrels of flour by shipping the barrels out of the country to a third person not authorized by the owner). That person can be said to have exercised dominion, control, and custody of the flour barrel and converted it to his own use. *Id.*Suppose, however, that the barrel of flour could be copied like a data file? If the

Suppose, however, that the barrel of flour could be copied like a data file? If the true owner can still use or sell his flour barrel and the flour is not diminished, if the original flour barrel is not interfered with in any way, can the person with the duplicate barrel of flour be said to be exercising dominion, custody, and control over the original flour barrel? In other words, does copying a data file without more, constitute the

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Plaintiff cites attorney Sharp's own declaration (¶¶ 14 & 15, which, in turn, cites as an exhibit a letter that attorney Sharp sent to defense counsel and a letter from defense counsel to Sharp).

The evidence offered indicates that Defendant Jimenez-Maggiora communicated with William Mobley, M.D., of UCSD, on August 25, 2015. Defendant Jimenez-Maggiora advised Mobley that he intended to copy approximately 25 "datasets," listing them by name. See Decl. of J. Daniel Sharp in Supp. of Opp'n. to Defs.' Mot. to Clarify or Modify the Prelim. Inj. (filed 9/29/15), Ex. G (Dkt. #31-4 at 51-60). The datasets are described as a subset of the ADNI dataset and a compressed copy of the copied files was attached to a follow-up email to Mobley. *Id.* Defense counsel's letter thereafter explained that the copied files were part of the collection of ADNI study data. See Decl. of J. Daniel Sharp in Supp. of Opp'n. to Defs.' Mot. to Clarify or Modify the Prelim. Inj. (filed 9/29/15), Ex. H (Dkt. #31-4 at 62-63). The ADNI study, in turn, is a project of NCIRE which has transferred its research contract to Defendants Aisen and USC, according to the letter. Id. If this is true (and Plaintiff identifies no evidence to the contrary), then the preliminary injunction order specifically excepts such acts of access, custody, or control. Paragraph 1 of the order explains, "[t]his order does not determine the rights of third parties, and shall not be construed to preclude any third party [such as NCIRE] from assigning to Defendants any rights that such third parties may have to obtain access, custody, or control over ADCS data." The evidence suggests this is exactly what happened with the copying of files from "adcs-adni2.iadcs.org," and the copying was consistent with the preliminary injunction order. In other words, this is not clear and convincing evidence of contempt.

As a final example, Plaintiff contends that a letter from USC to the ADCS

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exercise of dominion, custody or control over the original data file? The motion assumes without discussion that copying data *does* constitute exercising dominion, custody and control.

Steering Committee dated October 2015 "is proof that Defendants are willfully refusing to comply with the [preliminary injunction order]. . . ." The letter, however, appears to be a defensive explanation describing how Defendants, on the contrary, have complied with the premininary injunction and are trying to protect the safety and fidelity of the Alzheimer's research data while attempting to work with UCSD officials. See Decl. of J. Daniel Sharp in Supp. of Mot. for Sanctions (filed 11/16/15), Ex. F (Dkt. #51-4). Like the other examples, it is not clear and convincing evidence of contempt.

VI. CONCLUSION

To borrow a phrase: contempt of a court order is a serious charge, and requires serious proof. *United States v. Castro-Ponce*, 770 F.3d 819, 823 (9th Cir. 2014) ("Obstruction of justice is a serious charge, and requires serious proof."). And not just serious proof, but clear and convincing proof. *Stone*, 968 F.2d at 856 n.9. And the movant must prove contempt of *a specific and definite order*. *Id*. Plaintiff has not carried its burden.

As mentioned above, medical research is complicated and large scale data management is complicated. Questions are inevitable and deliberation takes time. Defendants have taken an acceptable course by continuing to communicate with the Special Master and seeking clarification or modification from the Court in view of changed circumstances – a change in circumstances anticipated in the preliminary injunction order. Plaintiff has cited no similar case where contempt sanctions were imposed. The motion for contempt sanctions is denied.

DATED: September 6, 2016

Hon. Roger T. Benitez United States District Judge

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